UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
MONROE DIVISION

ALICIA SMITH, CAROLINA BOURQUE, EMMA BURKEY, CHRISTOPHER CODY FLINT, MICHELLE ZIMMERMAN, PhD, ERIN RHODES, JESSICA KROGMEIER, LORIN JEPPSEN, and REACT19, INC., *Plaintiffs,* -vs.- **UNITED STATES OF AMERICA, UNITED STATES HEALTH RESOURCES AND SERVICES ADMINISTRATION, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and JOHN DOES 1-3,** *Defendants.*	Case No. 3:23-cv-01425 Judge Elizabeth E. Foote Magistrate Kayla D. McClusky

PLAINTIFFS' MEMORANDUM IN SUPPORT OF THEIR MOTION FOR DECLARATORY RELIEF AND PRELIMINARY INJUNCTION

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INTRODUCTION

During the COVID-19 pandemic, Americans "experienced the greatest intrusions on civil liberties in the peacetime history of this country." *Arizona v. Mayorkas*, 143 S. Ct. 1312, 1314 (2023) (Gorsuch, J., concurring). The government's failure to provide adequate and timely compensation to those injured by COVID-19 vaccines—vaccines the government mandated in many cases—represents the climactic chapter of the long parade of civil rights violations related to the vaccine rollout. Plaintiffs request that this Court enjoin the federal government from ongoing constitutional violations, cutting off the bleed of the irreparable harm Plaintiffs continue to suffer each day.

Plaintiff Emma Burkey was a healthy 18-year-old high school student with a 4.3 GPA before she "did the right thing" and received a COVID-19 vaccine. ECF 18, *Pls.' 1st Am. Verified Compl.* ("**Compl.**") ¶¶ 52. 54. Within weeks of vaccination, Emma was placed in a medically induced coma and had undergone three brain surgeries. *Id.* ¶¶ 55-67. Due to what happened to Emma and similar harm to five others, use of the brand of COVID-19 vaccine they received was paused, ending with an admission by federal health authorities that there was a causal relationship between this COVID-19 vaccine and this type of injury. Emma's previously bright future has evaporated. Due to the catastrophic injuries the government's policies caused, her parents will have to care for her for the rest of her life, which will entail hourly care and significant medical expenses they cannot afford. The other Plaintiffs have similar devastating stories.

Because the government immunized vaccine manufacturers from liability, those injured by COVID-19 vaccines have only one option to seek redress: filing a claim in the Countermeasures Injury Compensation Program ("**CICP**"). While CICP gives citizens the right to compensation for their injuries, it is a sham process that provides no realistic remedy for the harms caused. The

government spent tens of billions of taxpayer dollars to purchase the COVID-19 vaccines and then mandated those vaccines on more than 100 million citizens; however, Defendant Health Resources and Services Administration ("**HRSA**") budgeted only $5 million and $7 million for "administration" of CICP in 2022 and 2023, respectively.[1] Of its multi-million-dollar administrative costs, it remains unclear what portion of those, if any, HRSA has allocated to actually pay injury claims. Unsurprisingly, given the underfunding and sheer number of Americans injured by the vaccines, there is a less than 1 percent chance of recovering any compensation in CICP. The handful of claimants approved for compensation have received an average payout of only $2,951.84.

Those attempting to navigate CICP are deprived of substantive and procedural safeguards, a reality experienced by Plaintiff Cody Flint and all others brave enough to wade into the system. Before receiving a COVID-19 vaccine, Cody was a healthy father and pilot. Compl. ¶ 76. Because of his injuries, Cody likely will never fly again and has already spent his family's entire savings on medical bills, including his children's college tuition fund. *Id.* ¶ 85. Cody filed a CICP claim, which was summarily denied with reasoning that cannot withstand even minimal scrutiny. *Id.* ¶¶ 82-83. However, because there is no judicial oversight of CICP, Cody has no avenue to rebut the government's shoddy justifications. His claim was determined entirely off the record. During the CICP process, he was unable to challenge or even learn the identities of the individuals making decisions related to his claim, was unable to review the documentation relied upon by government officials to deny his claim, was unable to seek confirmation that those deciding his case did not

[1] *See FY 2023 Operating Plan*, HRSA, https://www.hrsa.gov/about/budget/operating-plan (last accessed October 26, 2023).

possess conflicts of interest, was unable to present expert witnesses in support of his claim, and is prohibited from appealing the decision to a court of law.

For the reasons more fully outlined below, Plaintiffs possess clear entitlement to injunctive relief under the Fifth and Seventh Amendments. CICP bars Plaintiffs from any meaningful relief while refusing to provide even the most basic of due process protections, including notice and the opportunity to be heard at a meaningful time and in a meaningful manner. CICP also provides no "reasonably just substitute" or "reasonable alternative remedy" for taking Plaintiffs' state or common-law rights to recover damages. And CICP precludes Plaintiffs from exercising their constitutional right to a jury trial that would exist under state law and at common law. Accordingly, Plaintiffs request that the Court grant their motion for injunctive relief.

STATEMENT OF FACTS[2]

A. Liability Protections Under the Vaccine Act and PREP Act

Congress passed the National Childhood Vaccine Injury Act of 1986 ("**Vaccine Act**") after an avalanche of lawsuits threatened the financial viability of vaccine manufacturers.[3] The Vaccine Act effectively immunizes vaccine manufacturers from liability for vaccine injuries their products cause.[4] In return, Congress established a no-fault compensation system through which the federal government compensates those injured by vaccines. When it was passed, Congress recognized that

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[2] Plaintiffs incorporate by reference the allegations in their First Amended Verified Complaint as if fully set forth herein.

[3] *See, e.g.*, *Reyes v. Wyeth Labs*., 498 F.2d 1264, 1297 (5th Cir. 1974) (upholding jury verdict against vaccine manufacturer for injuries caused by polio vaccine); *Kearl v. Lederle Labs*., 172 Cal. App. 3d 812, 819 (1985) (discussing whether strict liability can attach to vaccine manufacturers).

[4] *See generally* 42 U.S.C. § 300aa-11(a)(2) (dictating liability protections for vaccine manufacturers); *see also* 42 U.S.C. § 300aa-22(b)(1) (dictating that vaccine manufacturer shall not "be liable in a civil action for damages arising from a vaccine-related injury or death"); 42 U.S.C. § 300aa-23(d)(2) (dictating that vaccine manufacturers cannot be liable for punitive damages related to injuries caused by their products in most all circumstances).

many of the vaccines covered by the Vaccine Act were "unavoidably unsafe." *See Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 254 (2011). When a claim is filed under the Vaccine Act, the U.S. Department of Health and Human Services ("**HHS**") is tasked with challenging the claimant's entitlement to relief, and the federal government steps into the shoes of the vaccine manufacturers to defend their products against injury claims in proceedings subject to specialized rules before the United States Court of Claims ("**Vaccine Court**").[5]

Although the Vaccine Act permits judicial review of decisions through the Vaccine Injury Compensation Program ("**VICP**"), VICP's flaws have been well documented and examined by Congress. Compl. ¶ 164 (referencing H.R. Rep. No. 106-977 (2000), https://www.govinfo.gov/app/details/CRPT-106hrpt977). In short, vaccine-injured children face the full weight of the federal government when seeking compensation for their injuries through VICP. *See Id.*

Two decades after the Vaccine Act, Congress created CICP pursuant to the Public Readiness and Emergency Preparedness Act of 2005 ("**PREP Act**"), Pub. L. No. 109-148, 42 U.S.C. §§ 247d-6d, 247d-6e (2005). CICP was established under the PREP Act to provide "timely, uniform, and adequate compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure." 42 U.S.C. § 247d-6e(a). The PREP Act authorizes the Secretary of HHS to issue a declaration that "a disease or other health condition or other threat to health constitutes a public health emergency." *Id.* at § 247d-6d(b). The PREP Act provides immunity to "covered persons" from liability under federal and state law for "all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by

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[5] *See, e.g.*, *Frequently Asked Questions: Covered Vaccines*, HRSA, https://www.hrsa.gov/vaccine-compensation/faq (last accessed Oct. 25, 2023) (stating that "settlements are not an admission by the United States or the Secretary of Health and Human Services that the vaccine caused the petitioner's alleged injuries.").

an individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure." *Id.* at § 247d-6d(a)(1). CICP claims must be filed within one year of administration of the vaccine. 42 U.S.C. § 239a(d).

Because Plaintiffs suffered injuries stemming from COVID-19 vaccines which were received pursuant to an HHS-declared public health emergency, their right to legal relief is currently limited by the PREP Act and, specifically, by CICP. *See generally* Compl. Five individual Plaintiffs submitted requests for CICP benefits. *Id.* ¶¶ 49, 75, 82, 97, 131. Three others did not file within the strict one-year statute of limitations because they were unaware of the program. *Id.* ¶¶ 38, 117, 145. This is not uncommon. Whether potential claimants lack knowledge of CICP, have no confidence in the program, or their symptoms develop or continue to progress beyond the one-year deadline, a substantial number of the vaccine-injured never file CICP claims. *See Id.* ¶¶ 38, 147 (outlining Plaintiff Smith's symptoms occurring outside the one-year statute of limitations and citing a survey showing that more than 40% of React19's membership was unaware of CICP's existence).

B. Lack of Government Transparency Concerning COVID-19 Vaccines

On December 8, 2020, then-President Trump proclaimed that COVID-19 vaccines had been developed at "breakneck speed" in "less than nine months," boasting that before Operation Warp Speed, "the typical timeframe for development and approval, as you know, could be infinity" and that the Administration was "pushing [the FDA] hard" so distribution could "immediately begin."[6]

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[6] *See Remarks by President Trump at the Operation Warp Speed Vaccine Summit,* White House Archives (Dec. 8, 2020), https://trumpwhitehouse.archives.gov/briefings-statements/remarks-president-trump-operation-warp-speed-vaccine-summit/.

Despite the fact that the clinical trials did not test the vaccines' ability to stop infection and transmission of COVID-19,[7] the Food and Drug Administration ("**FDA**") first granted emergency use authorization ("**EUA**") and subsequently reviewed and licensed the Pfizer-BioNTech vaccine in just 108 days.[8] The licensure was followed by mandates on over 100 million citizens. When concerned independent health professionals and scientists across the country sought to examine the data relied upon to license the Pfizer vaccine, the government initially refused to release the records. During protracted Freedom of Information Act ("**FOIA**") litigation seeking to obtain the data, the government argued it should be given at least 75 years, until 2096, to release the documentation. A federal judge rejected the government's proposal and ordered that the FDA release the entirety of the requested documents at 55,000 pages per month. *See Pub. Health & Med. Pros. for Transparency v. FDA*, No. 4:21-cv-1058-P, 2022 U.S. Dist. LEXIS 5621 (N.D. Tex. Jan. 6, 2022).[9]

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[7] FDA Briefing Document for Pfizer-BioNTech COVID-19 Vaccine, December 10, 2020, at p. 48 available at https://www.fda.gov/media/144245/download ("Data are limited to assess the effect of the vaccine against transmission of SARS-CoV-2 from individuals who are infected despite vaccination"); *see also https://multimedia.europarl.europa.eu/en/webstreaming/special-committee-on-covid-19-pandemic_20221010-1430-COMMITTEE-COVI* at 15:22:58-15:23:19, 15:31:47-15:33:39 (Janine Small, Pfizer's President of International Markets, testifying before the European Parliament and answering "No…. We had to really move at the speed of science," in response to a question from Member of the European Parliament Rob Roos, "Was the Pfizer COVID Vaccine tested on stopping the transmission of the virus before it entered the market?"); Rob Roos MEP (@Rob_Roos), Twitter/X (Oct. 11, 2022), https://bitly.ws/Yvsf.

[8] *See* Press Release, Pfizer, Pfizer and BioNTech Initiate Rolling Submission of Biologics License Application for U.S. FDA Approval of Their COVID-19 Vaccine (May 7, 2021), https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-initiate-rolling-submission-biologics; Press Release, FDA, FDA Approves First COVID-19 Vaccine (Aug. 23, 2021) https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine (announcing approval of Pfizer's COVID-19 vaccine 108 days after Pfizer initiated rolling submission of its BLA application). *See also* Press Release, Congressman Ralph Norman, Rep. Norman Introduces Legislation to Expedite FDA Compliance with FOIA Requests for Vaccine Approval Data (Dec. 2, 2021), https://norman.house.gov/news/documentsingle.aspx?DocumentID=1087.

[9] Similarly, the government battled transparency regarding data relied upon to license the Moderna vaccine, arguing in FOIA litigation that it should be given approximately 23.5 years to release that documentation

Safety signals arose soon after the COVID-19 vaccines were administered. Vaccine Adverse Event Reporting System ("**VAERS**"), established in 1990 and jointly overseen by the Centers for Disease Control and Prevention ("**CDC**") and FDA, was quickly overwhelmed with reports of adverse events. To date, there have been 1,664,184 adverse event reports related to the COVID-19 vaccines made to VAERS,[10] including the VAERS reports submitted by several Plaintiffs. *See* Compl. ¶¶ 44, 79, 109, 123. VAERS is known to be severely underreported.[11]

The safety concerns evidenced by VAERS are reiterated by CDC's v-safe data. Just days after President Trump's Operation Warp Speed announcement, on or around December 13, 2020, CDC introduced its smartphone-based program for COVID-19 vaccine recipients called "v-safe." The program allows users to "quickly and easily share with CDC how [they] feel after getting a COVID-19 vaccine."[12] Unlike VAERS, v-safe was not meant to capture only adverse event reports but instead aimed to gather general health information following every COVID-19 vaccine administered. Of the over 10 million v-safe users, more than 7.7% reported a health event requiring

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to the public. Fortunately, the government was ordered to release all the Moderna data within two years. *See Pub. Health & Med. Pros. v. FDA*, No. 22-cv-0915-P, 2023 U.S. Dist. LEXIS 82290, at *1 (N.D. Tex. May 9, 2023).

[10] https://wonder.cdc.gov/vaers.html (reflecting 1,664,184 events reported from COVID-19 vaccines as of October 25, 2023); *see also* https://www.medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=DIS&EVENTS=ON&VAX[]=COVID19&VAX[]=COVID19-2&VAXTYPES=COVID-19 (utilizing government's raw data but allowing users to save and send hyperlinks to searches and reflecting 1,664,184 events reported from COVID-19 vaccines).

[11] *See, e.g.*, Blumenthal et al., *Acute Allergic Reactions to mRNA COVID-19 Vaccines*, JAMA (Apr. 20, 2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7941251/?report=reader (noting a significantly higher rate of anaphylaxis than the rate reported by CDC); Lazarus et al., *Electronic Support for Public Health-Vaccine Adverse Events Reporting System (ESP: VAERS) – Final Report*, AHRQ (2010), https://digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf (reflecting that fewer than 1% of adverse events are reported to VAERS).

[12] *See* CDC V-Safe Informational Flyer, *available at* https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/pdfs/v-safe-information-sheet-508c.pdf.

medical attention, emergency room intervention, and/or hospitalization.[13] An additional over 25% of users missed school or work, and/or were prevented from doing normal activities.[14]

Unlike the VAERS data, however, the v-safe data was shielded from the public. Only after well over 100 million Americans received COVID-19 vaccines, and as part of protracted FOIA litigation, did CDC finally disclose a portion of the troubling v-safe records to the public.[15] However, despite the 7.7% serious adverse event rate—which when extrapolated to the number of fully vaccinated in the United States[16] indicates that 20,807,492 Americans have suffered adverse events seriously enough to need to seek medical care—just under 13,000 have submitted claims to CICP.

C. Federal COVID-19 Vaccine Mandates and Suppression of Free Speech Regarding Vaccine Injuries

Despite these risks, the government issued vaccination mandates that reached well over 100 million citizens: First, the Occupational Safety and Health Administration ("**OSHA**") mandated that all U.S. employers with at least 100 employees receive a COVID-19 vaccine. *See BST Holdings, L.L.C. v. OSHA*, 17 F.4th 604, 618 (5th Cir. 2021). Second, President Biden mandated that almost all federal employees, healthcare workers, and federal contractors receive a

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[13] *See V-safe COVID-19*, CDC, https://data.cdc.gov/Public-Health-Surveillance/v-safe-COVID-19/dqgu-gg5d (last updated July 25, 2023); *see also V-safe Data*, ICAN, https://icandecide.org/v-safe-data/ (in health impacts tab, select "Required medical care" from "Impact Category") (last accessed Oct. 25, 2023).

[14] *See V-safe COVID-19*, CDC, https://data.cdc.gov/Public-Health-Surveillance/v-safe-COVID-19/dqgu-gg5d (last updated July 25, 2023); *see also V-safe Data*, ICAN, https://icandecide.org/v-safe-data/ (in health impacts tab, select "Unable normal activities" and "Missed work/school").

[15] *Pub. Health & Med. Pros. V. FDA*, No. 4:22-cv-0915-P, 2023 WL 3335071, at *2 (N.D. Tx. May 9, 2023).

[16] Ultimately, 270,227,181 Americans completed the primary series of COVID-19 vaccines, and 676,728,782 doses have been administered. *See* CDC, *Covid-19 Data Tracker, available at*: https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-people-booster-percent-pop5.

COVID-19 vaccine. *Feds for Med. Freedom v. Biden,* 63 F.4th 366, 370 (5th Cir. 2023); *see also Kentucky v. Biden,* 23 F.4th 585, 603 (6th Cir. 2022). Plaintiff Krogmeier, a nurse, received the Pfizer vaccine with the understanding that vaccination would be required for any healthcare position she sought when returning to work from a recent childbirth. Compl. ¶ 120. Plaintiff Zimmerman received a COVID-19 vaccine after the White House issued a directive for states to prioritize vaccinating teachers. *Id.* ¶ 88. Both were severely injured. *Id.* ¶¶ 90-95, 123-128. Third, vaccination mandates were placed on the entire military.[17] Plaintiff Jeppsen, a member of the Air National Guard, was subject to the mandate and observed that the military was issuing blanket denials of religious exemption requests. Compl. ¶ 136. He did not pursue a religious exemption request, instead submitting to compelled vaccination against his better judgment, and was severely injured. *Id.* ¶¶ 134-143. Fourth, the government imposed a vaccination mandate on more than 7 billion people if they desired to enter the country.[18]

The government also violated the First Amendment freedoms of Americans who were injured by the vaccines and who sought to speak publicly about their injuries. *See Missouri v. Biden*, 80 F.4th 641 (5th Cir. 2023) (holding that the government violated the First Amendment freedoms of citizens through, *inter alia*, censoring viewpoints on social media platforms, including censorship of those who attempted to raise awareness of adverse side-effects of the COVID-19

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[17] Memorandum from Secretary of Defense to Senior Pentagon Leadership Commanders of the Combatant Commands Defense Agency and DOD Field Activity Directors, subject: Mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Members, (Aug. 24, 2023), https://media.defense.gov/2021/Aug/25/2002838826/-1/-1/0/MEMORANDUM-FOR-MANDATORY-CORONAVIRUS-DISEASE-2019-VACCINATION-OF-DEPARTMENT-OF-DEFENSE-SERVICE-MEMBERS.PDF.

[18] *See* Amended Order Implementing Presidential Proclamation on Advancing the Safe Resumption of Global Travel During the COVID-19 Pandemic, 87 Fed. Reg. 20405 (Apr. 4, 2022), https://www.cdc.gov/quarantine/pdf/CDC-Vaccine-Order-04-04-2022-p.pdf.

vaccines); *see also Exhibit A*, Dressen Decl. ¶ 7; *Dressen v. Flaherty*, Action No. 3:23-CV-155 (S.D. Texas 2023) (case brought by vaccine-injured citizens alleging First Amendment violations where government forced social media platforms to censor posts about their vaccine injuries, treatments, and legal recourse). The censorship made it increasingly difficult for those injured to share with one another, among many other things, knowledge about CICP and evidence to help support their needed claims of causation for requests for benefits from the program.

D. CICP's Lack of Substantive and Procedural Safeguards

On the heels of "the greatest intrusions on civil liberties in the peacetime history of this country," *Mayorkas*, 143 S. Ct. at 1314 (Gorsuch, J., concurring), Plaintiffs find their claims for COVID-19 vaccine injuries channeled through CICP, a nonjudicial process, rather than a VICP proceeding in Vaccine Court, or elsewhere. As of October 1, 2023, 12,233 CICP claims have been filed related to COVID-19 countermeasures. CICP has compensated only **six** of those claims, with an average payout of $2,951.84.[19] Almost 90% (10,966/12,233) of the COVID-19 countermeasure claims remain "pending review or in review."[20] In rare instances where a decision has been reached, almost 98% of the COVID-19 countermeasure claims have been denied (1,235/1,267). CICP has awarded compensation to 0.05% of total claimants (6/12,233), almost 3 years after the vaccines were being administered to the public.[21] It is unsurprising that only a handful of claims have been paid and that many others remain pending review; due to underfunding, the government could never provide just and reasonable compensation to the number of Americans who have been injured by a COVID-19 vaccine. Defendant HRSA budgeted only $5 million and $7 million for

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[19] *See* https://www.hrsa.gov/cicp/cicp-data/table-4.

[20] *See* https://www.hrsa.gov/cicp/cicp-data.

[21] *Id.*

"administration" of CICP in 2022 and 2023, respectively.[22] Ninety-four percent of CICP's budget is spent on administrative costs, rather than on compensation for victims. *See* Compl. ¶ 160-61.

The entire CICP process is shrouded in secrecy. The government does not disclose the identity of individuals who make CICP determinations. Compl. ¶ 133, Ex. 14. CICP holds no hearings and operates entirely off the record. *See Id.* Ex. 5. Claimants whose requests are denied cannot appeal to a court of law.

While CICP claimants are subject to an extremely narrow 1-year statute of limitations for filing claims and a 60-day deadline to request reconsideration, CICP itself is not subject to any formal deadlines for deciding claims. For the past two years, Plaintiff Burkey has repeatedly inquired when her CICP claim would be decided and was told it would be a "hot minute." Compl. ¶ 75. In the over 18 months since submitting her CICP claim, Plaintiff Bourque has also repeatedly inquired when a decision would be made and has been told "we don't really have a time frame." *Id.* ¶ 49 and Ex. 2. Plaintiffs have no way of tracking requests until they receive a case number, at some uncertain time in the future, and CICP administrators have a history of losing records and of supplying conflicting guidance. *Id.* ¶¶ 97-101 and Exs. 7-9. Under CICP, only serious physical injuries and deaths are compensable,[23] whereas under the VICP, a broader range of injuries are compensable.[24]

CICP claims under the PREP Act stand in stark contrast to traditional VICP claims under the Vaccine Act. Some of the most critical differences follow:

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[22] HRSA, FY 2023 Operating Plan, *available at:* https://www.hrsa.gov/about/budget/operating-plan.

[23] *See Id* at § 247d-6e(e)(3).

[24] *See* Comparison of CICP and the Vaccine Act, *available at* https://www.hrsa.gov/cicp/cicp-vicp.

First, CICP claims must be filed within a strict 1-year statute of limitations, triggered by the date of vaccination and unrelated to the manifestation of any symptoms, while claims for vaccine injuries under VICP may be filed up to 3 years after manifestation of symptoms. *Compare* 42 U.S.C. § 239a(d), *with* 42 U.S.C. § 300aa-16(a).

Second, petitioners in VICP know the identity of the Special Masters who will be deciding their claims. The decision-makers within CICP are unknown to the public and to claimants, and claimants cannot determine whether the decision-makers have conflicts of interest.

Third, the Vaccine Act calls for VICP claims to be decided by Special Masters within 240 days, not at some uncertain date in the future. *See* 42 U.S.C. § 300aa-12(d)(3). This is consistent with the legislative intent behind the Vaccine Act to establish a no-fault compensation system "designed to work faster and with greater ease than the civil tort system." *Bruesewitz*, 562 U.S. at 228.

Fourth, in many cases, VICP claimants can forego proof of causation by utilizing the vaccine injury table. *Id.* (citing 42 U.S.C. § 300aa-11(c)(1) and § 300aa-13(a)(1)(A) and (B)). HHS has provided no CICP injury table for COVID-19 vaccines to date.

Fifth, attorneys' fees are provided under VICP, not only for successful cases, but even for unsuccessful claims that are not frivolous. *See* 42 U.S.C. § 300aa-15(e). This incentivizes attorneys to assist those submitting petitions in VICP. There is no option for attorneys' fees under CICP and, therefore, most claimants are left on their own to navigate the CICP system.

Sixth, once a VICP claim is filed in the U.S. Court of Federal Claims, there are processes in place by which claimants are able to present their own evidence and experts and can obtain and

challenge the government's evidence and positions.[25] No such opportunity exists in CICP for claimants to see or challenge the government's evidence or to identify their expert(s).

Seventh, CICP is a payor of last resort and only provides for out-of-pocket medical expenses and lost wages up to $50,000/year, whereas VICP provides for out-of-pocket medical expenses, lost wages (with no $50,000/year cap), pain and suffering, and future medical care expenses. For people with life-altering injuries who require future care, life care plan values can be in the tens of millions of dollars over an injured person's lifetime.

Eighth, VICP claims are entitled to judicial review of the special master's decision in the Court of Federal Claims. *See* 42 U.S.C. § 300aa-12(e), (g); *see also Luez v. Sec'y of HHS*, 63 Fed. Cl. 602, 611 (2005) (noting that the Vaccine Act "provides the parties with the ultimate hearing: a judicial forum in which to litigate the question of eligibility"). None of these procedural safeguards or attributes are available for CICP claimants.

E. Ongoing and Irreparable Harms Suffered by Plaintiffs

Plaintiffs in this case are a small cross-section of tens of thousands of Americans impacted by the PREP Act and CICP. Each individual Plaintiff has suffered severe injuries that impacts his or her daily life. *See generally* Compl. ¶¶ 33-145. Emma Burkey was a healthy Nevada high school student before receiving the J&J COVID-19 vaccine. After three brain surgeries and thousands of hours of physical therapy, she struggles to walk, write, or care for herself. *Id.* ¶¶ 69-71. Since receiving the Pfizer vaccine, Alicia Smith has been diagnosed with Bell's palsy, myoclonus

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[25] *See, e.g.,* Vaccine Rules, Court of Federal Claims, *available at* https://www.uscfc.uscourts.gov/sites/default/files/vaccine_rules_20230731.pdf (detailing processes for claimants under the Vaccine Act to present evidence, request a hearing, make legal arguments, challenge the government's positions, rebut expert opinions, conduct discovery, and ability to access the government's records relied upon to rebut their claim).

(involuntary irregular twitching of a muscle or joint), thyroid dysfunction, and lumbar spondylosis (degeneration of the spine). She is unable to continue her career full-time as a hairdresser and has struggled to find re-employment due to her health limitations caused by the vaccine. *Id.* ¶¶ 34-37. Cody Flint's vaccine injuries cost him 80% of his income and his job as a crop-dusting pilot. *Id.* ¶ 85. Michelle Zimmerman suffered irreversible brain and vision damage and continues to be medically disabled. *Id.* ¶¶ 90-92. Each Plaintiff has incurred, and continues to incur, medical bills and other expenses ranging from tens of thousands to hundreds of thousands of dollars. *Id.* ¶¶ 38, 48, 73-74, 85, 114, 129, 144. Plaintiff React19,[26] whose members reside in all 50 states, is comprised of more than 36,000 individuals who were injured by a COVID-19 vaccine. *Id.* ¶¶ 10, 146; *Exhibit A*, Dressen Decl. ¶ 4.

CICP presents insurmountable obstacles impacting Plaintiffs' day-to-day lives. Without compensation, Cody Flint cannot obtain medical treatment needed to restore any hope that he could fly again. Compl. ¶¶ 81, 85. Erin Rhodes has drained retirement accounts and faces the prospect of losing her home. *Id.* ¶¶ 114-115. Michelle Zimmerman's life is on hold until she can obtain additional funds for medical treatment for her substantial injuries. *Exhibit B*, Zimmerman Decl. ¶ 24. Plaintiffs all require medical care to get their health to a point where they can work again as they used to and support themselves and, for some, their families. *Id.* ¶¶ 48, 69-74, 85, 111, 127-129, 144.

While these irreparable harms persist, several Plaintiffs continue to wait for CICP decisions. Michelle Zimmerman and Jessica Krogmeier submitted their claims over two years ago. Compl. ¶¶ 96, 131. Emma Burkey and Carolina Bourque submitted their claims 19 and 23 months

[26] *See* https://react19.org/about.

ago, respectively. *Id.* ¶¶ 49, 75. For those in the CICP process, there is no end in sight. *See Id.* ¶ 75 (CICP representative stating that it will be "a hot minute" until Emma Burkey's claim is decided); *Id.* ¶ 49 and Ex. 2 (CICP representative stating that "we don't really have a time frame" for deciding claims); *Id.* ¶ 132 and Ex. 13 (CICP representative stating "there is no timeline" for deciding the claim).

Each individual Plaintiff faces significant, ongoing physical injuries. Emma Burkey has endured three brain surgeries and thousands of hours of physical therapy. Her life is now defined by a continued fight to regain motor function, walking with the help of a cane and a brace, and struggling to use the restroom without assistance. Compl. ¶ 69-71. Michelle Zimmerman is medically disabled from permanent brain and vision damage, unable to work, drive, or walk for more than a few minutes at a time. *Id.* ¶ 6. She can no longer live independently. *Id.* ¶ 93. Erin Rhodes is constrained most days to her bed and electric wheelchair. *Id.* ¶ 116.

Many Plaintiffs suffer severe financial burdens as well. Alicia Smith has spent over $25,000 on medical bills and faces significant employment limitations due to her ongoing symptoms. Compl. ¶¶ 37-38. Jessica Krogmeier has lost $35,000 per year in earning potential and was forced to withdraw $10,000 from her 401(k) to make ends meet. *Id.* ¶ 129. Carolina Bourque spent over $30,000 and continues searching for effective medical treatments. *Id.* ¶ 48. Emma Burkey's parents have incurred hundreds of thousands of dollars in debt and will forego retirements in their ongoing attempts to aid her recovery. *Id.* ¶ 73-74. Cody Flint already spent his family's savings and his children's college fund, so he cannot afford necessary medical treatment. *Id.* ¶ 85. And Erin Rhodes cashed out her retirement accounts, faces the prospect of losing her home, and cannot afford necessary medications. *Id.* ¶¶ 111, 115.

LEGAL STANDARD

To obtain a preliminary injunction, a movant must show: (1) a substantial likelihood of success on the merits; (2) a substantial threat of irreparable injury; (3) that the threatened injury if the injunction is denied outweighs any harm that will result if the injunction is granted; and (4) that the grant of an injunction will not disserve the public interest. *Louisiana v. Biden*, 55 F.4th 1017, 1022 (5th Cir. 2022) (quotation marks omitted).

Regarding the first element, a heightened standard applies where, as here, a party requests a mandatory injunction seeking to upend the status quo. In such cases, the moving party must establish a "clear entitlement to the relief." *Justin Indus., Inc. v. Choctaw Secs., L.P.*, 920 F.2d 262, 268 n.7 (5th Cir. 1990). However, the Fifth Circuit has stated a preliminary injunction is appropriate where, like here, the status quo is clearly causing irreparable injury. *See Canal Authority of the State of Florida v. Callaway*, 489 F.2d 567, 576 (5th Cir. 1974) (when examining a request for a mandatory injunction, "the focus always must be on prevention of injury by a proper order, not merely on preservation of the status quo").

The Fifth Circuit and its district courts carefully examine cases challenging the status quo and have issued mandatory injunctions where constitutional rights are at play. *See, e.g.*, *Byrum v. Landreth*, 566 F.3d 442, 449 (5th Cir. 2009) (reversing district court's denial of a preliminary injunction sought under the First Amendment and ordering a preliminary injunction against a 17-year-old statute prohibiting the use of the phrase "interior designer" by unlicensed professionals); *Speaks v. Kruse*, 445 F.3d 396, 402 (5th Cir. 2006) (ordering a preliminary injunction against a 14-year-old chiropractor solicitation law challenged under the First Amendment); *Bosarge. v. Edney*, 2023 U.S. Dist. LEXIS 67439 (S.D. Miss. April 17, 2023) (on First Amendment grounds, issuing injunction against Mississippi's mandatory vaccination policy for schoolchildren,

upending 40-year status quo).

ARGUMENT

I. PLAINTIFFS POSSESS A CLEAR ENTITLEMENT TO RELIEF UNDER THE FIFTH AND SEVENTH AMENDMENTS

A. CICP Fails to Provide Minimum Procedural Due Process Protections

The Fifth Amendment states that no citizen may be deprived of life, liberty, or property without due process of law. U.S. Const. amend. V. "The Constitution… requires the government to provide procedural safeguards to protect against the erroneous deprivation of substantive rights." *Little v. Frederick*, 2020 U.S. Dist. LEXIS 21949, at *26 (W.D. La. Feb. 7, 2020). Procedural due process claims require two inquiries: (1) "whether there exists a liberty or property interest which has been interfered with" by the government, and (2) "whether the procedures attendant upon that deprivation were constitutionally sufficient." *Kentucky Dep't of Corr. v. Thompson*, 490 U.S. 454, 460 (1989).

CICP implicates recognized property interests. The government extinguished Plaintiffs' common law tort claims and replaced them with a federalized tort claim requiring proof of causation, a claim that has no discernible value. The Supreme Court has long recognized that a cause of action is a species of property protected by the Due Process Clause. *See Logan v. Zimmerman Brush Co.*, 455 U.S. 422, 428 (1982); *see also Tulsa Prof'l Collection Serv. v. Pope,* 485 U.S. 478, 485 (1988) (holding that "little doubt remains" that a cause of action is a Constitutionally protected property interest); *Blackmon v. Am. Home Prods. Corp*., 328 F. Supp. 2d 647, 656 (S.D. Tex. 2004) (recognizing that a claim brought under the Vaccine Act "is a property interest protected by the Due Process Clause" (citing *Mullane v. Central Hanover Bank & Trust,* 339 U.S. 306 (1950)); *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 807 (1985); *Duke Power Co. v. Carolina Envtl. Study Grp*., 438 U.S. 59, 94 (1978) (stating that the Price-Anderson

Act's elimination of common law-based tort claims was a recognized property right and that the "Act impinges on that right by limiting recovery in major accidents" (Stewart, J., concurring)). In addition, CICP also fails to provide procedural safeguards related to Plaintiffs' substantive due process rights to informed consent and to a just and reasonable substitute to their tort claims the government extinguished. *See infra*, § I.B.[27]

1. CICP Fails to Provide Even Basic Procedural Safeguards

"The touchstone of due process is protection of the individual against arbitrary action of government." *Jauch v. Choctaw Cnty.*, 874 F.3d 425, 430 (5th Cir. 2017). "The essential requirements of due process are notice and an opportunity to respond." *McDonald v. City of Corinth, Tex.*, 102 F.3d 152, 155 (5th Cir. 1996). An opportunity to respond must come "at a meaningful time and in a meaningful manner." *Mathews v. Eldridge*, 424 U.S. 319, 3354 (1976). The United States Supreme Court has considered three factors to determine whether government action satisfies due process requirements:

> First, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards; and finally, the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail.

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[27] CICP also implicates profound liberty interests. The PREP Act preempts standard informed consent requirements under state common law and then, for all intents and purposes, eliminates informed consent at the federal level. As a result, 270 million American injected vaccines without informed consent; in fact, the government fought to hard to ensure information necessary for citizens to make informed healthcare decisions would be hidden for 75 years. *See Pub. Health & Med. Pros. for Transparency,* 2022 U.S. Dist. LEXIS 5621. This implicates recognized liberty interests. *See Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 269 (1990) (holding that the right to refuse life-saving medical treatment is a liberty interest protected by the Fifth Amendment on grounds that the right to die is a "logical corollary of the doctrine of informed consent", a doctrine that "has become firmly entrenched" in the American legal system, and reasoning that every "human being of adult years and sound mind has a right to determine what shall be done with his own body").

Mathews, 424 U.S. at 335. When subjected to the *Mathew*s factors, it is clear CICP violates Plaintiffs' procedural due process rights.

a) Plaintiffs' substantial interest in relief

Plaintiffs' private interests in this case are beyond substantial. Under the PREP Act, Plaintiffs' sole remedy for injuries from COVID-19 vaccines is to pursue their claim in CICP. Each Plaintiff suffer injuries that substantially impacts his or her daily life. *See generally* Compl. ¶¶ 34-147. They have incurred, and continue to incur, medical bills and other expenses ranging from tens of thousands to hundreds of thousands of dollars, and their careers have been severely impacted, and in some cases, destroyed. Compl. ¶¶ 37, 47, 72-73, 84, 113, 125, 139. Without compensation, Cody Flint cannot obtain necessary medical treatment to restore even the slim hope that he could ever fly again. *Id.* ¶¶ 80, 84. Erin Rhodes has drained retirement accounts and faces the prospect of losing her home. *Id.* ¶¶ 113-114. Michelle Zimmerman and the other Plaintiffs' lives are each on hold until they can obtain additional funds for medical treatment for their substantial injuries. All Plaintiffs require medical care to get their health back to a point where they can work or pursue education again. For most Plaintiffs, their families' livelihoods are also at stake. *See Phillips v. Vandygriff*, 711 F.2d 1217, 1222 (5th Cir. 1983) (acknowledging the principle that a person has a liberty interest in pursuing an occupation).

As such, each Plaintiff has a substantial interest in obtaining relief, whether through a functioning CICP program or some other remedy. However, CICP either denies those injured a remedy, or issues functional denials through bureaucratic delays. *Mathews*, 424 U.S. at 341 (holding that the "possible length of wrongful deprivation . . . is an important factor in assessing the impact of official action on the private interests.").

Plaintiffs also represent, at a minimum, tens of thousands of Americans who have suffered an injury after "doing the right thing" and receiving a COVID-19 vaccine. Over 12,000 Americans have asserted their rights in CICP and there are likely many more who, for various reasons, did not file a claim but who are or were eligible, including because they are unaware of CICP, know it is futile to submit a request, or could not file because symptoms of their adverse reaction manifested outside of CICP's one-year statute of limitations. *See* Compl. ¶¶ 38, 117, 145, 147; *Exhibit A*, Dressen Decl. ¶¶ 5, 8-9.

b) CICP's established record of erroneous deprivation and the value of additional or substitute safeguards

CICP fails to meet the PREP Act's stated objective of providing "timely, uniform, and adequate compensation" to individuals injured by a COVID-19 vaccine. *See* 42 U.S.C. § 247d-6e(a). Because of CICP's non-existent procedural safeguards, the program will always generate "erroneous deprivations" of recognized liberty and property interests. *Mathews*, 424 U.S. at 335. Accordingly, it is essential to implement additional procedural safeguards—at a minimum, safeguards substantially similar to those contained in VICP. While suffering from life-altering injuries, Plaintiffs' requests for information about CICP and attempts to receive compensation have been consistently ignored, delayed, or denied, without any meaningful opportunity to be heard or to challenge those making decisions on their claims. In short, the risk of "erroneous deprivations" of rights is baked into the fabric of CICP.

Further, in clear violation of elementary due process principles, CICP does not disclose the identity of individuals who make eligibility determinations, does not provide the information relied upon for the decision, and does not permit vaccine injured citizens to challenge the government's evidence. Compl. ¶ 132-133; *see also Id.* Exs. 13-14. CICP holds no hearings and operates entirely off the record. Claimants have no way of determining who decision-makers are and whether they

have conflicts of interest. CICP does not publicly disclose any medical standards on which decisions are based and provides no COVID-19 injury table for establishing damages. *Id.* ¶ 99 and Ex. 8. If CICP denies a claim, it does not disclose the information, expert reports, or opinions that justify the denial. *See Id.*; *see also Id.* Ex. 5.

CICP also fails to provide the opportunity for judicial review. Compl. ¶¶ 83-84. Once denied, claimants can request "reconsideration" within 60 days, but once again, the government does not disclose whether the same individual(s) consider the appeal, who the decision-makers are, or whether they have conflicts of interest. *See Id.* Ex. 14. The process is not fair, and there is no avenue to challenge the inequities. *Mathews*, 424 U.S. at 343 (stating that "the fairness and reliability of the [challenged] procedures" is a critical factor in determining whether procedural due process has been satisfied).

Cody Flint's case brings into sharp focus the need for additional procedural safeguards, including access to judicial oversight. Although Cody had over 10,000 flight hours and a decade of annual flight physicals demonstrating his excellent health before the COVID-19 vaccine, including one just 12 days before his COVID-19 vaccine, unnamed CICP officials determined that his vaccine injury was caused by "barotrauma," not the vaccine. Compl. ¶¶ 82-83 and Ex. 5. The unidentified CICP panel appears to have ignored Cody's longstanding clean bill of health before the vaccine, the fact that Cody's injury occurred **almost immediately** after he received the vaccine, and the fact that Cody could not suffer barotrauma in both ears from flying a crop-dusting plane at an altitude of 200 feet as he had done on thousands of previous flights. *Id.* Cody's own physicians ruled out the government's theory during their initial evaluation and instead determined that his injuries were vaccine related. *Id.* ¶ 83. Cody had no opportunity to attend a hearing, present witnesses, or question the purported CICP experts. Instead, he is left with a letter stating that an

unidentified panel determined he is not entitled to compensation for his injuries. *Id.* Ex. 5. *See Mathews*, 424 U.S. at 345-46 (observing the basic due process requirement for "full access to all information relied upon" by the government); *McDonald*, 102 F.3d at 155 ("The essential requirements of due process are notice and an opportunity to respond.").

CICP operates as a modern-day "star chamber" in which unidentified individuals review and decide claims, followed by the alleged review of any "appeals" (reconsideration requests) by an unidentified panel. *See, e.g.*, *Schultz v. Medina Valley Indep. Sch. Dist.*, No. SA-11-CA-422-FB, 2011 U.S. Dist. 140330 (W.D. Tex. Dec. 6, 2011) (noting that early Americans came to the United States to escape England's "star chamber of secret trials" (citing JOHN SOUTHERDEN BURN, THE STAR CHAMBER (2008))). CICP provides no clear legal standard for review. CICP refuses to identify those who make the initial decisions or consider any reconsideration requests. If there were judicial oversight, claimants like Cody Flint would be able to obtain compensation for the injuries caused. *See Mathews*, 424 U.S. at 349 (finding procedural due process satisfied where the option for judicial review of disability benefit decisions was available).

In addition, expedient decisions are paramount for the vaccine injured. However, CICP contains no safeguards to ensure claimants are timely compensated. Almost 90% of CICP claims for COVID-19 vaccine injuries remain "pending review or in review." Compl. ¶ 153. Emma Burkey is just one example of the more than 10,000 individuals whose CICP claims are pending review. Emma filed her CICP claim almost two years ago. *Id.* ¶ 75. She was only 18 years old when she suffered life debilitating injuries in the days after receiving the J&J COVID-19 vaccine. *Id.* ¶¶ 52, 54-62. The J&J vaccine rollout was halted nationwide by federal health authorities, in part, *because of* Emma's injuries. *Id.* ¶ 66. If CICP was a functioning program, Emma would have been compensated expediently. *See* 42 U.S.C. § 247d-6e(d). But CICP is not a functioning

program, and CICP representatives continue to report that it will be a "hot minute" until Emma's claim is decided. *Id.* ¶ 75. Meanwhile, her family's precarious financial situation continues to deteriorate. *See Mathews*, 424 U.S. at 341 (observing that the "possible length of wrongful deprivation" is critical to the procedural due process inquiry).

In rare instances where CICP actually makes a decision, over 97% of the COVID-19 vaccine injury claims have been denied. CICP has awarded compensation to approximately 0.05% of COVID-19 claimants (six in total). The average of these six payouts is $2,951.65. Benefit determinations remain pending for 0.2% of total COVID-19 claimants who have been approved (25 in total). Congress may have intended to provide "timely, uniform, and adequate compensation," but in practice, CICP simply delays requests until their inevitable denials. Even for those who may access the compensation they are entitled to, the caps on the amounts are exceedingly low. Annual lost employment income awards are capped at $50,000 per year and the standard maximum death benefit is $370,376.[28] In any event, CICP could never provide fair and just renumeration to the potentially millions of Americans entitled to compensation since Defendant HRSA budgeted only $7 million to the program for FY 2023, and in the past, 94 percent of its budget has been allocated to administrative costs.

Plaintiffs' unsuccessful attempts to navigate CICP demonstrate more than a mere possibility of a "risk of erroneous deprivation." The deprivations are established, ongoing, and imminent, and it is clear that the government is entirely disinterested in remedying these procedural deficiencies without court intervention. *Mathews*, 424 U.S. at 335.

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[28] *See* https://crsreports.congress.gov/product/pdf/LSB/LSB10584 at 3.

c) The government's interest

The governmental interest in ensuring that those catastrophically injured are timely and fairly compensated is of utmost importance. When Congress passed the PREP Act, it made its interests clear: to provide "timely, uniform, and adequate compensation" to those injured by "covered countermeasures," including COVID-19 vaccines. *See* 42 U.S.C. § 247d-6e(a).

In virtually identical circumstances, under the Vaccine Act and its VICP program, the administrative and fiscal burdens of implementing procedural safeguards for vaccine-injured Americans did not outweigh the public interest in instituting a fair and just compensation scheme. As such, Plaintiffs do not request enactment of an unduly burdensome process, nor do they seek novel or extraordinary due process protections.

Further, the extent of due process protections owed is a function of the magnitude of the deprivations at issue. *See Washington v. Harper*, 494 U.S. 210, 229 (1990) ("The procedural protections required by the Due Process Clause must be determined with reference to the rights and interests at stake in the particular case"); *see also Hernandez v. Cremer*, 913 F.2d 230, 237 (5th Cir. 1990). Large deprivations require greater procedural safeguards.

The government has already determined it is vital that those injured by vaccines are provided basic due process protections under VICP, including judicial oversight to check errant administrative decisions. *See, e.g.*, *Richardson v. Sec'y of HHS*, 89 Fed. Cl. 657, 660-61 (2009) (overturning administrative official's denial of compensation for VICP claim where the manner in which the bureaucrat had overseen the claim "eviscerate[d] the fairness of the proceedings" and therefore failed to satisfy basic due process requirements). Plaintiffs and countless others have been severely injured (or worse) by the COVID-19 vaccines, all with FDA's fast-tracked EUA, followed by government driven vaccine mandates. The government cannot now credibly argue it

is against the public interest to implement robust procedural protections for those catastrophically injured as a result of its policies. *See Mathews*, 424 U.S. at 335 (stating that the public interest element requires a weighing the societal benefits of implementing additional due process protections against the fiscal and administrative "burdens that the additional or substitute procedural requirement would entail").

2. CICP Violates Plaintiffs' Substantive Due Process Rights Because It Provides No Viable Avenue for Compensation for Their Injuries

The Due Process Clause guarantees more than a fair process; it also includes a substantive component that "provides heightened protection against government interference with certain fundamental rights and liberty interests." *Troxel v. Granville*, 530 U.S. 57, 65 (2000) (internal quotation marks omitted). The right to pursue redress for injuries or wrongs is a bedrock principle of America's legal system. The Supreme Court has upheld legislation that modifies or abrogates a common law right to a tort claim, provided that the legislature has replaced the extinguished right with a just and reasonable substitute. *See, e.g.*, *Duke Power*, 438 U.S. at 88 (stating that the Price-Anderson Act provided a "reasonably just substitute" for common-law or state law remedies for injuries related to nuclear accidents); *New York Central Railroad Co. v. White*, 243 U.S. 188, 202 (1917) (holding that New York's no-fault worker's compensation system was a "just settlement" for the common law tort claim the system modified). Critically, the replacement schemes in *Duke Power* and *White* were: (i) adequately funded, and (ii) incentivized responsible behavior. In *Duke Power*, the federal statute set a cap of $560 million in damages per incident, the majority of which would be paid by the party responsible for the injuries through direct payments or insurance premiums. 438 U.S. at 66. In *White*, New York's worker's compensation program guaranteed claim payments would be funded through "premiums received from employers." 243 U.S. at 194.

Here, the opposite is true. CICP is severely underfunded and rife with perverse incentives.

The average payout for COVID-19 CICP claims is $2,951.84, and less than 1 percent of CICP claimants filing claims related to COVID-19 countermeasures have received compensation. Compl. ¶ 153. This result is no surprise given HRSA's paltry 2023 budget of $7 million dollars. *Id.* ¶ 160. Because of the number of claims filed, there is simply no way those harmed by a COVID-19 vaccine could ever receive fair redress for the harms caused. If the current 12,233 claimants were all paid from the $7 million dollars, each would be able to receive a maximum of $572.22. And what little funds are allocated to CICP are extracted from the public, providing no deterrent for risky and socially destructive behaviors by the actors who caused the harms.

Additionally, CICP's strict one-year statute of limitations from the date of injection is also substantively unfair and serves to eliminate the tort claims of many Americans who suffered life-altering injuries, including those whose symptoms manifested outside the one-year limitation period and who were unaware of CICP, in part, because the government suppressed information about vaccine injuries. A statute of limitations cannot be so brief as it serves to "bar the existing rights of claimants without affording [the opportunity to assert the right in court]; if it should attempt to do so, it would not be a statute of limitations, but an unlawful attempt to extinguish rights arbitrarily." *Wilson v. Iseminger*, 185 U.S. 55, 62 (1902); *see also Reynolds v. Porter*, 760 P.2d 816 (Okla. 1988) (striking legislative modification to statute of limitations that lacked discovery rule provision as unconstitutional under the Oklahoma Constitution). FDA licensed the Pfizer vaccine in just 108 days. Troubling safety data was then concealed from the public. *See* discussion *supra* Statement of Facts, Section B. As such, there is absolutely no way for the population and those injured to fully comprehend the long-term risks and adverse side effects of the vaccines. *See Duke Power*, 438 U.S. at 88 (upholding Price-Anderson Act, which effectively institutes a three-year statute of limitations from the date on which the claimant first knew, or

reasonably could have known, of his injury or damage, and a limitations period that potentially extends to ten years after nuclear incidents).

In sum, the provisions of the PREP Act pertaining to CICP, including but not limited to 42 U.S.C. § 247d-6d, extinguished Plaintiffs' tort causes of action under state law.[29] CICP's provisions are arbitrary and capricious because, both facially and as applied to Plaintiffs, the program fails to provide a "reasonably just substitute" or "reasonable alternative remedy" for eliminating Plaintiffs' fundamental right to recover damages for their injuries. Unlike the Vaccine Act's judicial review process, CICP operates off the record, without meaningful notice to claimants and opportunity to be heard or appeal errant bureaucratic decisions. Plaintiffs cannot review the government's evidence, confront or question the government's experts or witnesses, present their case in court or in any formal hearing, and those injured by the pharmaceutical products whose injuries manifest outside of one-year from date of vaccination are prohibited from seeking redress for the life altering harms they are experiencing. CICP's 97.5% denial rate and *de minimis* compensation show that, in effect, CICP extinguishes Plaintiffs' legal claims for their injuries in exchange for no compensation. Thus, the entire CICP program is entirely arbitrary as it violates

[29] CICP also extinguishes state constitutional rights to a just alternative remedy. Where state legislatures interfere with a common law right, even modifications to common law causes of action are regularly struck down in state courts where a fair alternative is not supplied. *See, e.g.*, *Mello v. Big Y Foods, Inc.*, 826 A.2d 1117, 1124-25 (Conn. 2003) ("It is settled law that [the Connecticut Constitution] restricts the power of the legislature to abolish a legal right existing at common law prior to 1818 without also establishing a reasonable alternative to the enforcement of that right"); *Tillman v. Goodpasture*, 485 P.3d 656, 667 (Kan. 2021) (observing that, while the legislature can modify the common law right, it must provide "an adequate substitute remedy for the right infringed or abolished"); *Busch v. McInnis Waste Sys.*, 468 P.3d 419 (Or. 2020) (holding statutory damages cap unconstitutional under Oregon Constitution and, therefore, void); *Waite v. Utah Labor Comm'n*, 416 P.3d 635, 642 (Utah 2017) (holding Utah's Constitution requires "an effective and reasonable alternative remedy" where a common law right is abrogated). *See also Fein v. Permanente Med. Group*, 474 U.S. 892, 893-95 (1985) (White, J., dissenting from dismissal of appeal) (observing the open question whether due process forbids states from enacting damage caps without providing a *quid pro quo* to persons whose claims are capped).

the PREP Act's stated objective of providing "timely, uniform, and adequate compensation" to individuals injured by covered countermeasures. 42 U.S.C. § 247d-6e(a).

B. CICP Violates Plaintiffs' Seventh Amendment Right to a Jury Trial

The Seventh Amendment guarantees that, "In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise re-examined in any Court of the United States, than according to the rules of the common law." U.S. Const. amend. VII. The Seventh Amendment applies "to actions enforcing statutory rights, and requires a jury trial upon demand, if the statute creates legal rights and remedies, enforceable in an action for damages in the ordinary courts of law." *Curtis v. Loether*, 415 U.S. 189, 194 (1974). "In a just sense, the [Seventh] amendment then may well be construed to embrace all suits which are not of equity and admiralty jurisdiction, whatever may be the peculiar form which they may assume to settle legal rights." *Parsons v. Bedford*, 28 U.S. 433, 447 (1830). The Supreme Court has previously equated government benefits and entitlements with core private rights in certain circumstances. *See, e.g.*, *Goldberg v. Kelly*, 397 U.S. 254, 261-63 (1970) (cited in *Axon Enter. v. FTC*, 143 S. Ct. 890, 909 n.5 (2023) (Thomas, J., concurring)).

CICP does not merely strip Plaintiffs and others injured by COVID-19 vaccines of government benefits or entitlements. CICP displaces Plaintiffs' legal rights to litigate core private rights for negligence and claims for other injuries—rights that should be heard by a jury under the Seventh Amendment. Thus, the government is not merely conferring a benefit; the government is replacing a legal right for monetary damages with a purported benefit under CICP.

Negligence was a legal claim at common law that existed when the Seventh Amendment was adopted. The "origin of negligence cases dates back as early as the fifteenth century." Peter A. Arhangelsky, *Nullifying the Constitution: Federal Asbestos Tort Reform and the Abrogation of*

Seventh Amendment Rights, 40 Suff. U. L.Rev. 95, 114 (2006). "When the Seventh Amendment was enacted in 1791, personal injury cases sounding in negligence were ubiquitous in the English court system." *Id.* Juries decided these early negligence cases *See* Patrick J. Kelley, *Symposium, Restating Duty Breach, and Proximate Cause in Negligence Law: Descriptive Theory and the Rule of Law*, 54 Vand. L. Rev. 1039, 1057 (2001) (arguing that the early preference for jury trials was instrumental in shaping modern tort law).

Plaintiffs allege that they have suffered significant injuries from the COVID-19 vaccine. But for the PREP Act and the establishment of CICP, each Plaintiff could seek recovery of monetary damages for, among other things, physical injuries and loss of income or earning potential. CICP violates Plaintiffs' Seventh Amendment rights because it denies their right to a trial by jury.

II. THE REMAINING PRELIMINARY INJUNCTION FACTORS FAVOR RELIEF

A. Plaintiffs Have Suffered and Continue to Suffer Irreparable Injury

The loss of constitutional freedom constitutes irreparable injury. *Opulent Life Church v. City of Holly Springs, Miss.*, 697 F.3d 279, 294-97 (5th Cir. 2012) (citing *Elrod v. Burns*, 427 U.S. 347, 373 (1976)). As stated above, Plaintiffs have suffered irreparable injury because the PREP Act violates their constitutional rights under the Fifth and Seventh Amendments.

Plaintiffs have also suffered irreparable harm from the reduction or termination of medical benefits. *See LaForest v. Former Clean Air Holding Co.*, 376 F.3d 48, 56 (2d Cir. 2004) (affirming district court's finding of irreparable harm where plaintiffs would be forced to forego needed prescriptions); *Pashby v. Delia*, 709 F.3d 307, 329 (4th Cir. 2013) (affirming district court's finding of irreparable harm where plaintiffs presented evidence that they would lose "needed medical care" because of reduction in benefits). Plaintiffs have been severely injured by COVID-

19 vaccines and struggle to obtain adequate medical care. Carolina Bourque has already spent over $30,000 and struggles to find effective medical treatments. Compl. ¶ 48. Emma Burkey's parents have incurred hundreds of thousands of dollars in debt and must forego retirement in their ongoing attempts to aid her recovery. *Id.* ¶ 73-74. Cody Flint has already burned through savings and his children's college fund; he cannot afford necessary medical treatment needed to get back to work. *Id.* ¶ 85. And Erin Rhodes cashed out her retirement accounts and now faces the prospect of losing her home. *Id.* ¶ 115.

In the Medicare context, the risk of going out of business pending administrative appeals can constitute irreparable injury. *See Arthritis & Osteoporosis Clinic of E. Tex., P.A. v. Azar*, 450 F. Supp. 3d 740, 751 (E.D. Tex. 2020) (citing *Family Rehab., Inc. v. Azar*, Civil Action No. 3:17-CV-3008-K, 2018 U.S. Dist. LEXIS 108706, at *18 (N.D. Tex. June 28, 2018)). The same logic extends here where Plaintiffs face immense emotional, medical, and financial burdens without any realistic prospect of relief. CICP representatives have repeatedly acknowledged that there is no end in sight. Compl. ¶ 75 (stating that it will be "a hot minute" until Emma Burkey's claim is decided), Ex. 2 ("[W]e don't really have a time frame."), Ex.3 ("There's no time frame."), Ex. 13 ("There is no timeline…. [T]hey have however long they need to make a determination.").

In *A&O Clinic*, the plaintiff-medical clinic requested entry of an injunction to prohibit the federal government from recouping alleged overpayments pending its administrative appeal. The applicable regulations required that the administrative law judge hold a hearing within 90 days and complete the appeal within 180 days. *A&O Clinic*, 450 F. Supp. 3d at 746. When the process extended to almost three years, the clinic was nearly forced out of business. The district court reasoned the threat of business closure was sufficient to demonstrate irreparable harm. *A&O Clinic*, 450 F.Supp.3d at 749-50, 751 (internal docket citations omitted). The irreparable harm is

even more pronounced in this case, where Plaintiffs face the prospect of losing their homes, being unable to afford necessary medical care which will cause irreparable physical and emotional damage, and proceeding through the CICP program with virtually no chance of compensation.

B. The Balance of Harms and the Public Interest in Protecting Civil Liberties Weigh in Favor of Injunctive Relief

The balance of harms and public interest preliminary injunction factors likewise strongly favor an injunction. "These factors merge when the Government is the opposing party." *Nken v. Holder*, 556 U.S. 418, 435 (2009). An injunction will not disserve the public interest where "it will prevent constitutional deprivations." *Jackson Women's Health Org. v. Currier*, 760 F.3d 448, 458 n.9 (5th Cir. 2014) (citing *Awad v. Ziriax*, 670 F.3d 1111, 1132 (10th Cir. 2012) ("[I]t is always in the public interest to prevent the violation of a party's constitutional rights.")).

It must be emphasized that the public's interest and Plaintiffs' interests in this case are exactly the same—ensuring fair and timely compensation for those injured by COVID-19 vaccines. There is no competing harm to balance. Plaintiffs simply ask that the Defendants make good on their stated intention to timely and fairly compensate vaccine injured Americans. Each Plaintiff did the "right thing" and received the COVID-19 vaccine. And now each has been marooned into an endless cycle of delays in the CICP program with almost no chance of obtaining relief. Although CICP claims should be decided in a timely manner, several Plaintiffs have waited over 18 months (and some over two years) for a decision. Compl. ¶ 49, ¶ 75, ¶ 96, ¶ 131. There is no end in sight. *Id.* ¶ 75 (stating that it will be "a hot minute" until Emma Burkey's claim is decided). The equities clearly favor Plaintiffs in this case. Defendants' inability to run a functioning program is not grounds for ignoring Plaintiffs' claims. *See A&O Clinic*, 450 F.Supp.3d at 752 ("Defendants cannot shift the blame for the backlog to providers who are merely exercising their statutory rights under the system Congress established. It is up to Congress and the Secretary

to address the backlog, not A&O Clinic.").

CONCLUSION

Plaintiffs possess clear entitlement to declaratory and injunctive relief. CICP violates Plaintiffs' and others' rights pursuant to the Fifth and Seventh Amendments to the United States Constitution as it (i) fails to provide, among other things, the minimum procedural due process rights of notice and opportunity to be heard at a meaningful time and in a meaningful manner; (ii) provides no, or no meaningful, compensation for injuries; and (iii) violates their rights to a jury trial. Accordingly, Plaintiffs respectfully request this Court preliminarily enjoin Defendants from enforcing those provisions of the PREP Act which create the scheme providing liability protection and a compensation process for COVID-19 vaccines, including, but not limited to, 42 U.S.C. §§ 247d-6d and 247d-6e, until the federal government: (i) permits all COVID-19 vaccine injury claims to be adjudicated in Vaccine Court regardless of date of injury or prior filing in CICP; and/or (ii) reforms CICP to come into compliance with Constitutional requirements, including *inter alia* the minimal due process protections listed in paragraph 17 of Plaintiffs' Complaint. Compl. ¶¶ 17, 206-207.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 31, 2023 I presented the foregoing *Plaintiffs' Memorandum In Support of Their Motion for Declaratory Relief and Preliminary Injunction* to the Clerk of Court for filing and uploading to the CM/ECF system which will send notification of such filing to all parties or counsels of record, and I hereby certify that I have mailed by United States Postal Service this filing to the following currently non-CM/ECF participants:

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